THE CORRELATION BETWEEN END-TIDAL CARBON DIOXIDE MEASURED

BY CAPNOXYGEN$^{TM}$ MASK AND NASAL CANNULA

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**The use of capnography during general anesthesia has become a standard of care for all anesthesia providers and is considered an essential monitoring devise. The relationship of end-tidal carbon dioxide (ETCO2) to arterial carbon dioxide in intubated patients has been well established by Saunders, and colleagues (1994). Attention has focused on capnography in sedated, nonintubated patients where ETCO2 was not monitored and patients had associated comorbidities. Studies also have documented a correlation between the accuracy of ETCO2 to arterial carbon dioxide during spontaneous ventilation using a carbon dioxide (CO2) sampling device through a prong in an oxygen (O2) nasal cannula. In this study, a single-use medium concentration O2 face mask designed to deliver oxygen while monitoring ETCO2 in spontaneously breathing patients was used. The accuracy of the measured ETCO2 was compared to a standard nasal cannula sampling port in 13 normal healthy volunteers. There was a positive correlation between the ETCO2 of both devices with and without the addition of oxygen. Mean ETCO2 measurements with the mask decreased in proportion to increasing oxygen flows, while mean ETCO2 with the nasal cannula remained consistent. Sixty one percent of volunteers stated the mask was more comfortable to wear during their testing experience, and half stated they would prefer to wear the mask over the cannula for a procedure lasting more than one hour.**

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ABSTRACT

The use of **capnography** during general anesthesia has become a standard of care for all anesthesia providers and is considered an essential monitoring devise. The relationship of **end-tidal carbon dioxide** ($ETCO_2$) to arterial carbon dioxide in intubated patients has been well established by Saunders, and colleagues (1994). Attention has focused on capnography in sedated, nonintubated patients where $ETCO_2$ was not monitored and patients had associated comorbidities. Studies also have documented a correlation between the accuracy of $ETCO_2$ to arterial carbon dioxide during spontaneous ventilation using a carbon dioxide ($CO_2$) sampling device through a prong in an oxygen ($O_2$) **nasal cannula**. In this study, a single-use medium concentration $O_2$ face mask designed to deliver oxygen while monitoring $ETCO_2$ in spontaneously breathing patients was used. The accuracy of the measured $ETCO_2$ was compared to a standard **nasal cannula** sampling port in 13 normal healthy volunteers. There was a positive correlation between the $ETCO_2$ of both devices with and without the addition of oxygen. Mean $ETCO_2$ measurements with the mask decreased in proportion to increasing oxygen flows, while mean $ETCO_2$ with the nasal cannula remained consistent. Sixty one percent of volunteers stated the mask was more comfortable to wear during their testing experience, and half stated they would prefer to wear the mask over the cannula for a procedure lasting more than one hour.

Key Words**:** capnography, end-tidal carbon dioxide, nasal cannula

# THE CORRELATION BETWEEN END-TIDAL CARBON DIOXIDE MEASURED BY CAPNOXYGEN™ MASK AND NASAL CANNULA

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# FOREWORD

This research was conducted to provide information to all anesthesia providers who have strived to provide the best care possible to their patients during monitored anesthesia care procedures or conscious sedation.

# DEDICATION

I would like to dedicate this research to my two children, Kelly and Danny, who endured the long hours and the separation that was necessary to complete this project. Their strength and support allowed me to be successful. I would also like to that my committee members, as well as Captain Jane McCarthy, who helped in the genesis of this project.

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# CHAPTER I: INTRODUCTION

## Background of the Problem

End-tidal carbon dioxide ($ETCO_2$) measurement by a capnograph is a valuable monitor of patient ventilation during anesthesia. It is a gold standard of care recognized by the American Association of Nurse Anesthetists (1992) and the American Association of Anesthesiologists for all patients receiving general endotracheal anesthesia. Benumof (1998) states capnography should be considered an essential monitor always used by anesthesia providers.

Capnography is a method of measuring carbon dioxide ($CO_2$) in expired gas by the presence of a digital readout and plots airway $CO_2$ concentrations as a function of time. Before the 1960s many anesthesia providers assessed ventilatory adequacy by the presence of cyanosis (Wren, 1994). In 1966 findings on the reliability of capnography and its many applications in clinical practice were presented at a meeting of the Association of Anaesthetists of Great Britain and Ireland. Takki and associates (1972) demonstrated the reliability and validity of capnography in the estimating $ETCO_2$ during general anesthesia with intubated patients which was substantiated by other studies through the 1980s and early 1990s.

To improve patient safety and decrease anesthesia morbidity and mortality, attention focused on the use of capnogram monitoring in awake, nonintubated patients following Caplan and associates study describing 14 cases of sudden cardiac arrest in otherwise healthy patients who received spinal anesthesia (Caplan, Ward, Posner, & Cheney, 1988). The increase in outpatient surgery with frequent conscious sedation anesthesia during this time also sparked interest in methods to accurately measure $ETCO_2$

in nonintubated sedated patients.

Over the past decade studies demonstrated a range of accuracy of $ETCO_2$ compared to arterial carbon dioxide ($PaCO_2$) measurements obtained during spontaneous ventilation using a $CO_2$ sampling device attached to catheters positioned either in the nasal cavity or in the nasopharynx. Campbell, McLeod, Bissonnette, and Swartz (1994) found a high degree of reliability between $ETCO_2$ and $PaCO_2$ readings via a 5 cm 16 gauge catheter taped below the nares of 60 pediatric patients. Oberg, Waldau and Larsen (1995) found accurate and consistent $ETCO_2$ measurements could be obtained by a $CO_2$ sampling port inserted in a thin catheter in different locations between the hypopharynx and nasopharynx when compared to a nasal cannula sampling port. Conversely, Ivens, Verborgh, Phan Thi and Camu (1995) reported ETCO2 measurements during spontaneous ventilation with a nasal sampling device is affected by inadequate sampling of alveolar air, mixing of inspired and expired gases, and the occurrence of ambient air leaks in nonintubated patients. The authors said these variables made the use of an $ETCO_2$ nasal sampling device with an oxygen facemask a doubtful indicator of arterial $CO_2$ concentrations when compared to using a laryngeal mask airway. Three other studies found measurement mechanics can also affect the accuracy of $ETCO_2$ readings with a nasal sampling device (Brunner & Westenskow, 1988, From & Scamman, 1988, Fukuda, Ichinohe, & Kaneko, 1997). High ventilatory frequency, capnography transport delay, and supplemental oxygen, as well as patient variables such as nasal obstruction, a perforated septum, hypoventilation, and mouth breathing all lower ETCO2 measurements. These variables have made the use of the nasal sampling port problematic in awake, nonintubated patients especially children and patients with high respiratory

rates or mouth breathing.

There have been many anecdotal reports describing attempts made to control these variables. Some clinicians moved the nasal sampling port from nose to mouth when the patient converted to mouth breathing. Others have modified an existing oxygen mask by cutting it or attaching the capnograph probe to various locations inside the mask surface (Asai, 1994; Bromage, 1996; Inomata & Nishikawa, 1992; Langer, 1996; Bromage, 1996). While some investigators reported accurate $ETCO_2$ measurements following these modifications, others report problems with catheters occluding, kinking and falling out of the mask.

The correlation of $ETCO_2$ to arterial carbon dioxide ($PaCO_2$), which is considered the gold standard indicator of alveolar ventilation has been well described in endotracheally intubated patients undergoing mechanical ventilation (Saunders et al., 1994). Studies on the correlation of $ETCO_2$ to $PaCO_2$ measured by nasal or nasopharyngeal catheter devices in spontaneously breathing, nonintubated patients have documented wide variations in reliability. These variations may be due to patient to patient variability in oxygen administration, mouth breathing, ambient air leaks and catheter occlusion or displacement. The correlation of $ETCO_2$ to $PaCO_2$ with simultaneous oxygen administration in spontaneously breathing patients using a facemask specifically designed for both capnography and oxygen delivery functions has not been described. Nor is it known how well this device measures $ETCO_2$ compared to a nasal sampling catheter.

## Statement of the Problem

In 1998 CAPNOXYGEN™ LLC (Lebanon,TN) produced a unique clear resin single use facemask. The design of this facemask is specifically for delivering supplemental oxygen and monitoring $ETCO_2$ in spontaneously breathing nonintubated adult patients.

Design features include a bevel tip sample tube in the mid dome of the face mask which connects to any sidestream $CO_2$ sample system to via a female Luer connector on the CAPNOXYGEN™ mask. The mask is contoured to prevent ambient air leaks while delivering up to 6 liters/minute (L/min) of supplemental oxygen ($O_2$). A literature search on MEDLINE and CINNAHL (1990-2000) found no studies that evaluate $ETCO_2$ measurements with human subjects using the CAPNOXYGEN™ mask.

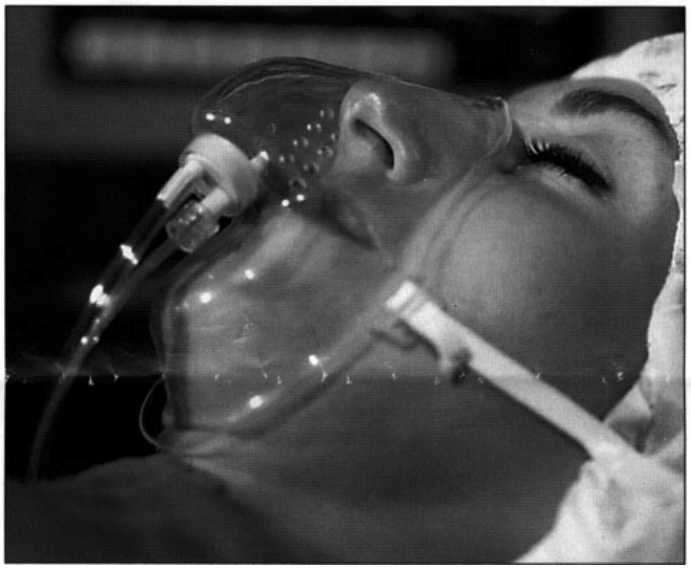


**Figure 1. The CAPNOXYGEN™ mask**

Source**:** With permission, CAPNOXYGEN™ LLC, (1998)-company product brochure.

## Aim of the Study

The aim of this study was to measure $ETCO_2$ measurements obtained by the CAPNOXYGEN™ (1998) mask. The measurements were correlated to $ETCO_2$ measurements obtained from a $CO_2$ nasal sampling port commonly used in operating rooms which has been found to be accurate (Campbell et al, 1994). $ETCO_2$ readings from the CAPNOXYGEN™ mask will be correlated to those of the nasal cannula sampling port.

## Research Questions

This study tested for the statistical significance of the coefficient of correlation between the two methods of measuring $ETCO_2$ by answering the following questions:

1. Is there a statistically significant difference in $ETCO_2$ measurements without supplemental $O_2$ between the CAPNOXYGEN™ (1998) mask compared to $ETCO_2$ obtained by a standard $CO_2$ sampling port inserted into one prong of a nasal cannula?

2. Is there a statistically significant difference between diluted (with $O_2$ flow) $ETCO_2$ measurements between the CAPNOXYGEN™ (1998) mask and nasal cannula catheter?

## Research Variables

The dependent variable identified in this study was $ETCO_2$ as measured by CAPNOXYGEN™ mask and nasal cannula with and without oxygen administration.

The independent variables identified in this study were the use of (a) the mask and (b) nasal cannula with a sampling port inserted into one prong to obtain $ETCO_2$ measurements.

## Conceptual Model and Theoretical Framework

The Betty Neuman Systems Model (Murray, 1998) is based on theories of stress adaptation. In the Neuman model, the person is viewed as a multidimensional whole, in constant dynamic interaction with the environment. Neuman defines a stressor as any environmental force that can potentially affect the stability of the system. Stressors may be intrapersonal, interpersonal, or extrapersonal. The Neuman s Systems Model was chosen as a conceptual framework for this study because of its orientation with systems theory, a method involving processes and outcomes that is well suited to anesthesia and the process of assessing and testing new equipment.

Three key concepts in Newman s theory are stress, homeostasis, and patient perceptions (Martin, 1996). The nurse s role in this model is to address variables affecting the patients response to stressors and reduce risk factors associated with them. The role of the nurse anesthetist within Neuman s framework is to support the normal line of defense of the client by impeding the stressors the client experiences. Within the framework of this study, these intrapersonal stressors could be defined as hypoxia, hypoxemia, and hypercarbia. Extrapersonal stressors could be defined as the nurse anesthetist s ability or inability to detect those threats during anesthesia care by obtaining accurate capnogram and capnography measurements. Homeostasis is a concept that is well integrated in anesthesia practice as evidenced by the constant vigilance required of the nurse anesthetist during the delivery of anesthesia care.

Neuman believes nurses receive training in the natural and behavioral sciences and are expected to conceptualize it in their own way (Martin, 1996). This point is very pertinent to the development of the product to be assessed in this study. According to

company spokesman, R. A. Davenport (personal communication, November 15, 1998), the CAPNOXYGEN$^{TM}$ (1998) mask was developed by a certified nurse anesthetist (CRNA) as a method to monitor capnography while providing oxygen to spontaneously breathing nonintubated patients.

## Definitions

The following are key words that were used in this study related to capnography:

### Conceptual Definition of Capnography

Capnography was defined as the nurse anesthetists interventions to monitor homeostasis and eliminate the stressors as previously noted.

### Operational Definitions

Capnogram. A graphic record of inspired and expired carbon dioxide concentrations in the form of continuous waves (Miller, 1992).

Capnograph. A monitor which produces a record of instantaneous $CO_2$ concentrations of inspired and expired gases by the absorption of infrared light by $CO_2$ as recorded on a capnogram (Miller, 1992).

Sidestream capnograph. This is also known as an aspiration capnograph, which continuously suctions gas from the breathing circuit into a sample cell within the capnometer monitor. $CO_2$ concentration is determined by comparing infrared light in a sample cell with a chamber free of $CO_2$ (Morgan & Mikhail, 1996).

Ohmeda Rascal II sidestram capnograph. The specific capnograph that was used to obtain ETCO2 measurements for this study. According to R. Kyle (personal communication, January 26, 2000), manager of the anesthesia simulator laboratory at USUHS, this model is calibrated by a company technician every six months according to

Ohmeda Corporation s specifications for validity and reliability. This model was recalibrated in April 2000 before testing began.

Capnometry. A device for measuring for measuring the end-tidal partial pressure of carbon dioxide ($ETCO_2$) (Miller, 1992).

End-Tidal Carbon Dioxide Tension ($ETCO_2$). The partial pressure of $CO_2$ in end tidal exhaled gas, which is primarily alveolar gas ($PACO_2$). $ETCO_2$ is used clinically as an estimate of $PaCO_2$ (Morgan & Mikhail, 1996).

## Assumptions

1. The capnometer and capnograph was calibrated accurately and the gas samples were obtained correctly as observed by an appropriate $ETCO_2$ waveform.

2. The CAPNOXYGEN$^{TM}$ mask and nasal cannula remained patent to accurately measure $ETCO_2$.

3. Volunteers who identified themselves as normal healthy subjects without any evidence of preexisting pulmonary or cardiac pathology or abnormalities were healthy and remained so during the study.

4. Volunteers rate and depth of respirations remained relatively consistent during data collection to provide accurate $ETCO_2$ measurements with both devices.

## Limitations of the study

1. In this study the CAPNOXYGEN$^{TM}$ mask was tested within the anesthesia simulator department of a university medical center with normal healthy volunteers. A larger study that includes testing in a clinical setting at multiple facilities would increase the generalizability of the results.

2. Subjects were experienced nurses who know that a nasal cannula delivers oxygen best if they nose breathe.

3. $ETCO_2$ was measured by nasal cannula as the dependent variable without correlating it to $PaCO_2$. While desirable, the actual measurement of $PaCO_2$ obtained via an arterial blood gas sample is invasive and potentially expensive. Moreover, the study sought to use normal healthy volunteers to eliminate extraneous variables caused by preexisting pulmonary and cardiovascular pathology, as well as the respiratory depressant effects of volatile anesthetics and narcotics. The intent of this investigation was to compare the capnography and oxygen administration functions of this new product to the method currently used in most anesthesia clinical settings.

# CHAPTER II: REVIEW OF THE LITERATURE

## Introduction

The purpose of this review is to identify relevant recent research about the measurement of $ETCO_2$ in spontaneously breathing patients. This review will provide insight into the problem of obtaining consistent $ETCO_2$ measurements with a nasal cannula, pharyngeal catheter, modified oxygen mask, or a nasal/oral discriminate sampling system, and lay the groundwork for investigating the correlation of $ETCO_2$ measurement by capnography oxygen mask and a $CO_2$ nasal sampling port.

## Review of the literature

Oberg et al.(1995) investigated the influence of nasal oxygen administration, position of a $CO_2$ sampling catheter, and mouth breathing on $ETCO_2$ measurements obtained from a pharyngeal catheter. In a study of nine healthy normal volunteers, they found reliable capnograph tracings were obtained from a thin catheter placed in different positions in an unintubated airway. Subjects received oxygen at a rate of two to 6.1 liters per minute (l/m) via nasal cannula without interference with the accuracy of the $ETCO_2$ measurements from the pharynx. Oberg and colleagues found the position of the catheter in either the hypopharynx, oropharynx, or nasopharynx had little effect on the $ETCO_2$, and concluded that the catheter could be placed where it causes the subject the least discomfort. The authors also found that mouth breathing caused a mean decrease in $ETCO_2$ of only 2.5 mmHg compared to nose breathing.

The study by Oberg et al.(1995) provided evidence of $ETCO_2$ reliability regardless of airway position or mouth breathing, its small sample size and use of a potentially irritating pharyngeal catheter in a nonintubated airway limited its usefulness. Further,

Bromage (1996) following Oberg and associates (1995) method, reported frequent patient discomfort and mucous obstruction when placing the $CO_2$ port deeper than 2 cm inside the external nares without any compensatory increase in the level of $ETCO_2$.

Campbell et al. (1994) examined the reliability of $ETCO_2$ as an estimate of $PaCO_2$ in spontaneously breathing infants and children. The $ETCO_2$ of 40 patients in a post anesthesia care unit (PACU) was obtained by a 5 cm 16 gauge catheter taped below the external nares, and this measurement was compared with the $PaCO_2$ drawn from an indwelling arterial line. Patients were equally divided into a group of 20 infants less than 12 kg and a group of 20 children greater than 12 kg. In addition, the investigators examined 20 additional patients during inhalation anesthesia. The $ETCO_2$ was measured from two locations: the proximal end of an elbow connector of a T-piece breathing system with a gas-sampling port in the elbow connector; and from a 5 cm 16 gauge cannula inserted through the sampling port. Campbell and associates found a correlation of .80 between $ETCO_2$ and $PaCO_2$ in PACU patients regardless of weight. The average $PaCO_2$ — $ETCO_2$ range was —0.6 $\pm$ 3.6 mmHg. Patients studied during mask anesthesia showed a stronger correlation between $ETCO_2$ and $PaCO_2$ when $ETCO_2$ was sampled from the cannula. The average $PaCO_2$ - $ETCO_2$ range was 3.5 $\pm$ 4.8 mmHg (cannula) and 8.6 $\pm$ 4.5 mmHg (elbow) ($P < 0.05$). The results suggested $ETCO_2$ monitoring was a reliable method for assessing adequacy of ventilation in spontaneously breathing children. These results were significant in a patient population that has a rapid respiratory rate who are obligate nose breathers with frequent nasal congestion, factors which could have reduced the correlation of $ETCO_2$ to $PaCO_2$. These findings

corroborated earlier studies of spontaneously breathing adults measured with a sampling port inside a nasal cannula.

Wright (1992) described the use of nasal capnography in monitoring heavily sedated emergency department adult patients. The prospective, noncontrolled clinical observational study monitored twenty-seven patients requiring sedation with benzodiazepines and/or narcotics for painful procedures. Ventilatory status was monitored by capnography by nasal cannula as well as pulse oximeter before, during, and after the administration of the sedative agents. The results were that the mean $ETCO_2$ increased 6.2% and $SaO_2$ decreased 3.7% during the procedures. One patient developed clinically significant apnea detected by apnea alarms on the capnometer and oximeter, and eight others developed clinically silent hypoxemia ($SaO_2$ less than 90% with no other physical or vital sign changes indicating cyanosis) with simultaneous increase in nasal $ETCO_2$. Wright concluded the use of pulse oximetry and capnography by nasal cannula is recommended for the detection of unrecognized hypoxemia during conscious sedation. He added that more research and clinical experience is required before routine use of capnography was recommended in the emergency department setting, as cannula occlusion is an occasional problem. This study emphasized the clinical significance of capnography as measured by a nasal cannula.

Saunders et al. (1994) investigated the accuracy of $ETCO_2$ compared to $PaCO_2$ in sleeping patients undergoing evaluation for sleep-disordered breathing and nocturnal ventilatory insufficiency. Capnograph readings were obtained for three groups of patients by a capnometer probe suspended in a loose-fitting aerosol facemask with extra holes cut out to minimize dead space. $ETCO_2$ measurements were made with

simultaneous arterial blood gas samples in 19 patients spontaneously breathing room air, (condition one), in 13 patients receiving supplemental oxygen via nasal cannula (condition two), and in 22 patients receiving nocturnal positive pressure ventilatory assistance (condition three). Saunders and colleagues found significant scatter in the $PaCO_2$ vs. $ETCO_2$ relationship. Only 23 % of the variability in $PaCO_2$ was explained by the variation of $ETCO_2$ in condition one, and only 15 and 20 % of the variability in $PaCO_2$ was explained by the variation of $ETCO_2$ during conditions two and three, respectively. Over 21% of patients had average $ETCO_2$ value in error by more than 10mmHg compared to $PaCO_2$ during condition one, 46.2% in condition two, and 63.7% in condition three. The authors concluded $ETCO_2$ measured with a facemask is not a consistently accurate reflection of $PaCO_2$ during sleep studies.

While Sanders et al. (1994) found a statistically significant variation in the $PaCO_2$-$ETCO_2$ relationship, the study failed to use a consistent method of oxygen administration and placement of the $CO_2$ sampling catheter between the three study groups. For example, patients in condition 2 had supplemental oxygen by nasal cannula with the $CO_2$ sensor hung suspended above in a loose fitting mask, while patient in condition 3 had positive pressure ventilation by a full facemask interface or by nasal cannula. The use of positive versus passive oxygen pressure and placement of the $CO_2$ catheter within a loose fitting mask with ambient air leaks may have increased the $PaCO_2$-$ETCO_2$ differences.

Another study by Ivens, et al. (1995) examined the relationship between $PaCO_2$ and $ETCO_2$ during inhalation anesthesia using a laryngeal mask airway (LMA) compared to facemask. Eighteen patients undergoing plastic surgery on an arm or leg were divided into two groups: nine patients had their airway maintained by a LMA, and nine received

an oral airway and facemask. Following induction, the airways of both groups were checked for leaks by auscultation and by manually increasing airway pressure up to 15 cm $H_2O$. Arterial blood gas samples were drawn at four different intervals during each procedure, while mean $ETCO_2$ measurements from the capnograph were averaged from all breaths occurring during a period of 20 seconds before the arterial blood sample. $ETCO_2$ sampling occurred at the standard proximal connector in the LMA group and between the mask and elbow piece in the facemask group. The authors found both $ETCO_2$ and $PaCO_2$ were higher in the LMA group: Pa-$ETCO_2$ differences ranged from 0.13 to 4.13 kPa in the facemask group, and from 0.0 to 1.73 kPa in the LMA group. Using pooled data regression analysis, Ivens and colleagues also found a better correlation coefficient was found in the LMA group ($r = 0.91$, $p < 0.001$) than in the facemask group ($r = 0.62$, $p < 0.01$). The authors concluded estimation of $PaCO_2$ by monitoring $ETCO_2$ is more reliable with a LMA than a facemask.

While the results of the Ivens et al. (1995) study were both clinically and statistically significant in a practice setting where an LMA is a viable option. During conscious sedation procedures, it may be impractical and unnecessary to use a LMA compared to nasal cannula or facemask.

Other studies have identified mechanical and physiologic variables in the measurement of $ETCO_2$ in sedated, spontaneously breathing patients that have been demonstrated to be unreliable when compared to the actual measurement of $ETCO_2$ in intubated patients. From and Scamman (1988) suggested respiratory rates greater than 30 breathes per minute lowers $ETCO_2$ due to gas mixing of adjacent tidal volumes within a nasal sampling catheter. Brunner and Westenskow (1988) state the effect of capnography

transport delay — the time needed to aspirate end-tidal gases through the sampling catheter — may also underestimate $ETCO_2$ values during rapid respiratory rates due to diluted gas in the sample catheter. Fukuda, et al.(1997) found the influence of both biological and mechanical factors can decrease the reliability of $ETCO_2$ measurements. Fukuda and colleagues suggest tidal volumes greater than 500 ml and respiratory rates less than 20 per minute, along with small diameter nasal prongs, shorter nasal cannula length, and smaller diameter nasal cannulas results in improved reliability of $ETCO_2$ measurements due to less dead space and turbulence within the cannula. Two other studies suggested that anatomic and physiologic changes in patients, including nasal obstruction, perforated septum, hypoventilation, large arterial to end-tidal carbon dioxide gradients, and mouth breathing, all lower $ETCO_2$ values, depending on the measurement method and site (Bhavani-Shankar, Moseley, Kumar, & Delph, 1988, Szaflarski & Cohen, 1991). In addition, obstruction of catheters, inconsistent measurement sites and dilution of $CO_2$ by supplemental oxygen are commonly cited problems that cause reduction in measurement accuracy.

Later studies described adaptations and modifications in equipment that occurred as anesthesia providers attempted to overcome the extraneous variables identified above as adversely affecting the correlation of $ETCO_2$ and $PaCO_2$. Anecdotal reports in the literature by Asai (1994), and Risdall and Geraghty (1994) found improved capnography tracings during regional anesthesia by connecting the $CO_2$ sensor through a vent hole in the body of a Hudson oxygen mask by removing the distal Luer connector and then reattaching it to the inside of the mask surface. Inomata & Nisikawa (1992) found success in attaching the $CO_2$ probe by a separate elastic strap under the patient s nostrils

inside a normal oxygen mask. They noted a leak around the facemask may have diluted expiratory $CO_2$, but the method was successful in detecting a 25 second period of apnea in a 71 year old man undergoing a hernia repair. Langer (1996) hypothesized that parturients often removed an oxygen mask modified for capnography during labor because it was too difficult to breathe. He reported acceptable capnography tracings and a 3-8 % increase in oxygen saturation by cutting a mask just above the vent holes to allow the quick elimination of $CO_2$, and applying the $CO_2$ sensor catheter loosely in the mask between the nose and upper lip. Langer failed to address the possible movement of the catheter inside the mask during active labor, and did not define acceptable capnograph tracings.

Only one study has attempted to limit the influence of mouth breathing by providing a new $ETCO_2$ measurement device capable of selectively sampling from either nasal and/or oral routes. Derrick, Waters, Kang, Cwalina and Simmons (1993) investigated the correlation of a nasal/oral discriminate sampling system (NODSS) to $PaCO_2$. The NODSS looks similar to a classic nasal cannula. Nasal prongs can be telescopically extended to maintain their position, and a multiperforated adjustable oral sampling cylinder is suspended between the upper and lower lip. Independent nasal and oral sampling lines are connected to a three-way stopcock to enable the operator to selectively sample each site independently or both sites simultaneously while delivering oxygen through one of the nasal prongs. Derrick and colleagues tested the device on twenty-four PACU patients divided into two groups based on health status and found a Pearson s product — moment correlation coefficient (r value) of 0.60 to 0.84 between $PaCO_2$ values for nasal and/or oral ETCO2 measurements. They also suggested there

was no significant difference between the mean Pa-$ETCO_2$ gradient compared to the mean gradient derived by the oral sampling port with this device ($P > 0.05$). The authors concluded the NODSS was a reliable, effective means of detecting respiratory inadequacy in spontaneously breathing patients.

In reviewing the data from the Derrick et al. (1993) study, it was interesting to note correlations to $PaCO_2$ were higher with the nasal sampling part of the NODSS with healthy patients, while patients with suspected pulmonary dysfunction more closely correlated with the oral part of the devise. This raises questions concerning the importance of measuring sites in relation to the patient respiratory functioning. Also of concern is the fact that there have been no subsequent studies on the device since the Derrick et al. study. While the company is still marketing the product as the Nazorcap Sampler (NasOrCap Medical, Inc., West Mifflin, PA, 1998) it is unclear if it is commonly used in clinical practice.

## Summary

Debate on the correlation of $ETCO_2$ to $PaCO_2$ as measured by a nasal cannula, pharyngeal catheter, modified oxygen mask, or nasal/oral discriminate sampling system exists in the anesthesia literature. No one method has sufficiently addressed technical or patient variables which has precluded the reliable estimate of $PaCO_2$ in spontaneously breathing nonintubated patients compared to intubated patients. While initial results of the NODSS looked promising, its application in clinical practice is unknown and the device has not been followed by further study. Studies by Caplan et al. (1988) and Wright (1992) illustrate the potential morbidity and mortality of patients not monitored for $ETCO_2$ during regional anesthesia or conscious sedation procedures. A need exists

for the investigation of a device that will address patient and technical variables outlined in this review and provide a consistent and more accurate means to monitor $ETCO_2$. It should also provide supplemental oxygen to the patient. Recently, a medical equipment manufacturer has designed and manufactured a new, improved mask, which is reported to be a more accurate method to monitor $ETCO_2$ while simultaneously providing oxygen. In this study I investigated the correlation of $ETCO_2$ measured by a capnography oxygen mask and nasal cannula.

# CHAPTER III: METHODOLOGY

## Introduction

In this chapter the methods that were used to determine the correlation between $ETCO_2$ by nasal cannula and CAPNOXYGEN™ mask by using each device on healthy volunteer subjects will be described. The research design, procedures, sample, measurement, and plan for data analysis will be described.

## Research Design and Procedures

Following submission and approval of this proposal by the Research Administration Department of the USUHS, data were collected at the anesthesia simulator department at USUHS during the month of April, 2000. The Institutional Review Board (IRB) was contacted as part of this process regarding the protection of human rights for the healthy volunteers for this study. Approval for the study was granted. Both devices have been used safely in clinical practice. Literature from CAPNOXYGEN™ LLC (1998) claims there are no contraindications for its use on human subjects, as the mask is made from a medical-grade resin and is latex-free. The safety of nasal cannulas has been well documented in the medical literature.

The CAPNOXYGEN™ mask was pilot tested on the anesthesia simulator machine and on two healthy subjects at the Uniformed Services University of the Health Sciences (USUHS) for patency and fit before it was used on human subjects as part of the study. $ETCO_2$ readings by the mask were correlated to $ETCO_2$ by nasal cannula with and without oxygen administration to establish a range of values to compare on human subjects. A standard nasal cannula was tested by inserting the lure end to an Ohmeda Rascal II sidestream capnograph. The $CO_2$ catheter was inserted into one of the prongs

of the nasal cannula by way of a 16-gauge angiocatheter intervenous needleset. The CAPNOXYGEN™ mask was similarly connected to the capnograph by attaching the male end of the $CO_2$ sample line to the female Luer connector on the mask. Oxygen was administered through a standard connection from the Ohmeda anesthesia machine to each device.

Following the completion of a brief health survey (see Appendix A) and informed consent form (see Appendix B), 15 healthy volunteers were asked to lie supine on a examination table in the anesthesia simulator laboratory and randomly select a number to determine whether they will be monitored with the CAPNOXYGEN™ mask or nasal cannula first. Subjects were asked to breathe normally for a period of two minutes with either device. The respiratory rate was determined by counting the respirations for 15 seconds and multiplying by four. Subjects were not asked to keep their mouth closed when using the nasal cannula. This might alter the variability inherent in patients who mouth breathe during conscious sedation. After a mean baseline $ETCO_2$ was established during a two-minute period without oxygen, oxygen was administered at 2, 4, and 6 liters per minute for a period of two minutes. At each level of oxygen administration, an average $ETCO_2$ reading was taken from either the nasal catheter $CO_2$ sensor or CAPNOXYGEN™ mask $CO_2$ sensor. Following a two-minute rest period, subjects were asked to breathe normally with the second device for two minutes, and then repeat the same sequence of oxygen administration and average $ETCO_2$ readings. After the procedure, subjects were asked to complete a brief questionnaire (see Appendix C) regarding the comfort and fit of each device. The entire procedure, including the completion of forms, took no more than 30 minutes for each subject.

## Sample

A convenience sample of graduate nursing students at the USUHS was taken following informed consent and satisfactory completion of a verbal health screening questionnaire. Exclusion criteria included a upper respiratory tract infection within 10 days of testing, asthma, smoking, or newly diagnosed pulmonary disease. All subjects had passed semiannual physical exam testing from their respective military services, and had an extensive physical exam screening before being accepted into their graduate education program at USUHS.

The class of 2001 USUHS graduate school of nurse anesthesia students were addressed at a meeting during March, 2000, and explained the purpose, methodology, and risks and benefits of the study and asked for volunteers. All students were given an equal chance to participate. All class members received an informed consent document (see Appendix B) to review at their convenience before consenting to participate in this study.

It was expected that differences in measurements between the two methods would be minimal and variation in differences among subjects would be small. With minimal differences and low variability of the differences, the standard error of the differences expected to be small, therefore, a small sample of approximately 15 subjects was justified.

## Measurement

Mean $ETCO_2$ measurements were recorded during two-minute intervals on a data flow sheet for each method of capnography (see Appendix D). A paired *t*-test was used to determine if there was a significant difference between the $ETCO_2$ measured by the CAPNOXYGEN$^{TM}$ mask and nasal cannula $ETCO_2$ measurement for each subject.

Statistical significance was accepted at a level of $p < 0.05$. In addition, correlations were determined between the CAPNOXYGEN™ mask and the nasal cannula for each $O_2$ flow.

## Data Analysis

Correlational research is conducted to examine linear relationships between two or more variables and to determine the type (positive or negative) and degree (strength) of the relationship (Burns & Grove, 1997). In this study a Pearson s product-moment correlation coefficient was used to examine the relationship between the two methods of capnography. A positive relationship was defined as one that indicates the variables vary together, where both $ETCO_2$ measurements either increase or decrease together. The negative or inverse relationship was defined where the two methods of $ETCO_2$ measurements vary in opposite directions; one variable will increase, the other will decrease. In this study, the strength of the relationship of $ETCO_2$ between the mask and nasal cannula could range from —1, a perfect negative correlation, to +1, a perfect positive correlation. A score of 0 would indicate there was no relationship between the two devices.

Results recorded on the data sheets were organized by a data dictionary to ease entry of data into a statistical package. The collected data were analyzed using the Statistical Package for the Social Sciences (SPSS), (April, 2000). A Pearson s product-moment correlation coefficient ($r$) was calculated between the mean $ETCO_2$ measurements for each $O_2$ flow for each subject. Using the criteria established by Burns and Grove (1997), an $r$ of 0.1 to 0.3 was considered a weak linear relationship, 0.3 to 0.5 a moderate linear relationship, and above 0.5 a strong linear relationship.

## Summary

This study was conducted using a descriptive correlational analysis to compare the $ETCO_2$ measured by CAPNOXYGEN™ mask to the $ETCO_2$ measured by a nasal cannula. A convenience sample of healthy volunteers was taken over a period less than one month at a university medical teaching facility. Data collection was done to compare the $ETCO_2$ measurements for each device, the strength of a linear relationship, and the percent of variance.

# CHAPTER IV. DATA ANALYSIS

## Introduction

In this chapter the results of the study will be presented. Data collection and analysis procedures will be discussed with respect to the aims of the study. Findings will be organized into meaningful groups for interpretation in Chapter Five.

## Characteristics of Study Sample

Thirteen subjects were recruited for the study. Eight males and five females ranged in age from 28 — 44 years old. Twelve subjects were active duty military nurses and one subject was an employee of the university s anesthesia department. All subjects completed a health questionnaire and identified themselves as healthy non-smokers without any physical or medical condition that could limit the rate and depth of their respiration. Subjects were also asked to complete a post-test questionnaire in which asked they rated each device according to fit and comfort.

## Data Analysis

During the data collection, the fraction of inspired oxygen ($FIO_2$), oxygen saturation ($SaO_2$), respiratory rate (RR), and end-tidal carbon dioxide ($ETCO_2$) of the subjects were recorded every 30 seconds during a two minute interval at each level of oxygen flow (see Appendix D). Extremely small variability between subjects with regard to $FIO_2$, $SaO_2$, and RR occurred during the two minute sampling intervals with both the nasal cannula and the CAPNOXYGEN$^{TM}$ mask. Therefore, these data will be referred to in the following chapter for trending purposes and will not be discussed here.

In analyzing the mean $ETCO_2$ measurements using the nasal cannula, there was a very small difference noted between the 13 subjects with and without oxygen flow.

Without oxygen flow, the mean $ETCO_2$ for the nasal cannula was 39.7, with a range of 7.3 (see Table 1). At the highest oxygen flow of 6 liters the $ETCO_2$ was 40.3, with a range of 12.5.

**Table 1.**

**Nasal Cannula Mean $ETCO_2$ Measurement by Oxygen Flow.**

| | $O_2$ flow (l/m) | | | |
|---|---|---|---|---|
| | 0 | 2 | 4 | 6 |
| Mean $ETCO_2$ (mmHg) | 39.7 | 40.7 | 41.0 | 40.3 |
| Standard Deviation | 2.89 | 3.39 | 3.60 | 3.91 |
| Minimum $ETCO_2$ (mmHg) | 36.3 | 34.3 | 36.8 | 34.3 |
| Maximum $ETCO_2$ (mmHg) | 43.5 | 46.0 | 47.3 | 46.8 |
| Range | 7.3 | 11.8 | 10.5 | 12.5 |

Mean $ETCO_2$ measurements with the CAPNOXYGEN™ mask were very similar to those of the nasal cannula without oxygen (see Table 2). Mean $ETCO_2$ was 40.6, with a range of 9.5. However, during oxygen administration, there was a significant and consistent decrease in $ETCO_2$ with increasing oxygen flow with the CAPNOXYGEN™ mask. Mean $ETCO_2$ at 2 liters was 36.8, at 4 liters was 35.2, and at liters was 33.0. The range of mean $ETCO_2$ values with the mask during oxygen flow was less than those of the nasal cannula at 6.0, 9.5, and 10.0, respectively.

**Table 2.**

**CAPNOXYGEN™ mask mean $ETCO_2$ measurement by oxygen flow.**

| | $O_2$ flow (l/m) | | | |
|---|---|---|---|---|
| | 0 | 2 | 4 | 6 |
| Mean $ETCO_2$ (mmHg) | 40.6 | 36.8 | 35.2 | 33.0 |
| Standard deviation | 2.73 | 1.78 | 2.46 | 2.89 |
| Minimum $ETCO_2$ (mmHg) | 35.5 | 32.5 | 31.5 | 29.3 |
| Maximum $ETCO_2$ (mmHg) | 45.0 | 38.5 | 41.0 | 39.3 |
| Range | 9.5 | 6.0 | 9.5 | 10.0 |

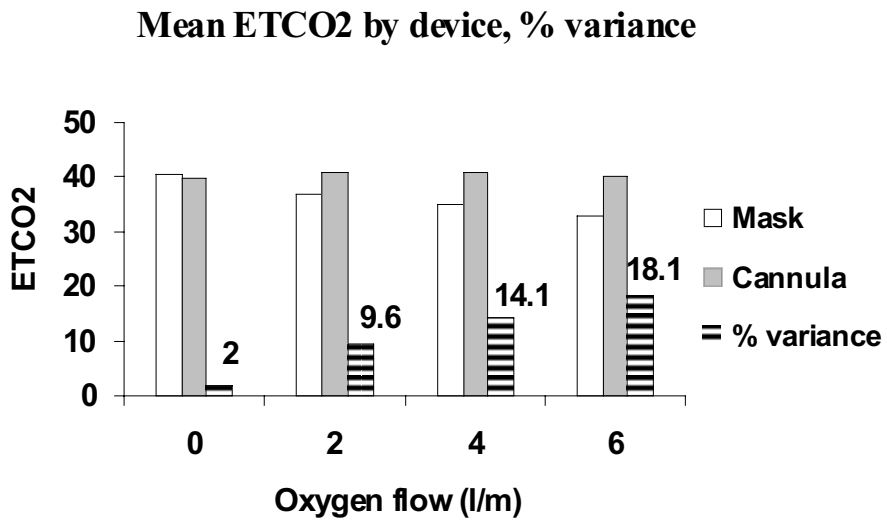
In comparing the mean $ETCO_2$ measurements of each device at each level of oxygen administration, there was a significant increase in the difference of $ETCO_2$ between the two devices as oxygen flow increased (see Table 3 and Figure 1). Without oxygen, the difference the mask and cannula was only 0.8 torr. However, when oxygen was added, mean $ETCO_2$ for the mask decreased significantly compared to nasal cannula. Mean $ETCO_2$ with the mask decreased 9.6% at 2 liters flow and 18.1% at 6 liters flow.

**Table 3.**

**Differences in mean $ETCO_2$ for mask and cannula by oxygen flow.**

| | $O_2$ flow (l/m) | | | |
|---|---|---|---|---|
| | 0 | 2 | 4 | 6 |
| Mask mean $ETCO_2$ (mmHg) | 40.6 | 36.8 | 35.2 | 33.0 |
| Cannula mean $ETCO_2$ (mmHg) | 39.7 | 40.7 | 41.0 | 40.3 |
| Mean difference | 0.8 | -3.9 | -5.8 | -7.3 |
| % variance mean difference | 2.0 | 9.6 | 14.1 | 18.1 |
| Standard deviation | 2.03 | 3.08 | 3.44 | 3.27 |
| Standard error mean | .56 | .85 | .95 | .91 |

**Figure 1.**




In correlating the $ETCO_2$ measurements of each device with and without oxygen, a strong positive linear relationship was found (Table 4). Without oxygen, Pearson s

product-moment correlation coefficient ( *r* ) was .74, with a two tailed test of significance ( *p* ) of .00. During oxygen administration of 2 and 4 liters per minute, the correlation was not statistically significanct. At two liters of $O_2$ flow, an *r* value of .43 (*p* = .14) was found and 4 liters per minute an *r* value of .40 (*p* = .17 ). However, at 6 liters per minute of oxygen administration, *r* increased to .57 ( *p* =.04).

**Table 4.**

**$ETCO_2$ Correlation of Coefficient for mask and nasal cannula by oxygen flow.**

| $O_2$ (l/m) | *r* | *p* |
|---|---|---|
| 0 | .74 | .00 |
| 2 | .43 | .14 |
| 4 | .40 | .17 |
| 6 | .57 | .04 |

In completing the post-testing questionnaire, the 13 subjects were asked Which device was more comfortable to wear during your testing experience and why?. Eight subjects (61%) stated the CAPNOXYGEN$^{TM}$ mask was more comfortable. Reasons stated included, There was no pulling on my ears or irritation to my nostrils at high flow rates like the nasal cannula, The cannula dried out my nose, The nasal cannula at six liters of flow hurt my nose, and I don t like things up my nose. Four subjects (31%) responded they preferred the cannula, stating the following reasons: The mask dried out my mouth more , The cannula was less restrictive and easier to draw a breath from; The cannula was just more comfortable to wear. One subject stated he did not prefer

either device, noting  The mask was claustrophobic, and the nasal  cannula was irritating to my nostrils.

When subjects were asked the question,  If this had been a conscious sedation or monitored anesthesia care procedure lasting more than one hour, which device would you prefer to wear?,  preferences for the two devices were evenly split. Seven subjects (54%) responded they preferred the mask, while six (46%) preferred the cannula.

When subjects were asked which device provided the best fit for administering oxygen and measuring end-tidal carbon-dioxide, eight (61%) stated the mask, while three (23%) stated the cannula.  One subject responded that the cannula provided the best fit for oxygen administration, while the mask provided the best fit for measuring end-tidal carbon dioxide.  One subject did not respond to the post-testing questionnaire.

When asked if they described themselves as nose breathers or mouth breathers at rest, all thirteen subjects stated they were nose breathers.  However, when asked if they deliberately tried to breathe through their nose while wearing the cannula, five subjects (39%) claimed they did, while eight (61%) stated they did not.

# CHAPTER V. SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

## Introduction

In this chapter, the data will be summarized and conclusions drawn from the study will be presented. Implications for clinical practice will be discussed as well as recommendations for future research.

## Conclusions

The aim of the study was to test $ETCO_2$ measurements obtained by the CAPNOXYGEN$^{TM}$ mask and correlate with them to those obtained from of a nasal cannula in 13 healthy normal volunteers. There was a strong, positive correlation between $ETCO_2$ measured by nasal cannula and CAPNOXYGEN$^{TM}$ mask with and without oxygen flow. $ETCO_2$ correlation was strongest and statistically significant without oxygen flow and at a flow of six liters of oxygen per minute. Correlations decreased slightly during oxygen flows of two and four liters per minute; however they remained in a moderate. linear relationship, as defined earlier in the study. The investigator cannot explain the small decrease in correlations at two and four liters per minute of oxygen between the two devices.

The clinical significance of the mean $ETCO_2$ measurement differences for each device should be emphasized. The nasal cannula provided a consistent mean $ETCO_2$ measurement during all levels of oxygen administration. The CAPNOXYGEN$^{TM}$ mask showed significant dilution of $ETCO_2$ as oxygen flows increased. I believe the decrease in $ETCO_2$ using the mask was due to a dilutional effect of oxygen in the mask. Clinicians using the CAPNOXYGEN$^{TM}$ mask should be aware that a decrease in capnometer

readings compared to nasal cannula does not necessarily indicate that their patient is hypoventilating.

The consistency of the mean $ETCO_2$ readings obtained by the nasal cannula must also be interpreted in the light of the fact 100% of study subjects identified themselves as nose breathers. Furthermore, 39% stated they deliberately tried to breath through their nose wearing the nasal cannula. The majority of these subjects were experienced clinicians who were aware that breathing through their nose would provide more accurate and consistent $ETCO_2$ readings with the nasal cannula. This may have influenced the effect of the consistent mean $ETCO_2$ measurements with the nasal cannula across all flows of oxygen.

As previously noted, the differences in the delivered $FIO_2$ and resulting $SaO_2$ for each device were small during oxygen administration. Average $FIO_2$ and $SaO_2$ at each level of oxygen flow were similar enough not to warrant an analysis for this study. This is not surprising, given all subjects were healthy and were not sedated during the testing. However, the added clinical variables of sedation and coexisting disease could have altered these results. In addition, mechanical differences between the two devices--the nasal cannula prongs have a much smaller diamenter compared to the mask tubing, and one of the prongs of the nasal cannula was partially occluded by the $CO_2$ sampling tube--could have played a larger role in delivered $FIO_2$ and $SaO_2$ when combined with the clinical variables mentioned above.

In discussing the study subjects preferences comparing the fit and comfort of each device, 61% preferred the fit of the mask over the cannula, 54% would prefer to wear the mask over the cannula for a monitored anesthesia case lasting over one hour, and 61%

thought the mask provided the best fit for delivering oxygen and monitoring $ETCO_2$. In analyzing the subjects responses, it is clear that preferences for the mask or the cannula were based on negative evaluations of the non-preferred device. The fact that there was a close preference for wearing the CAPNOXYGEN™ mask during procedures lasting longer than one hour may indicate a prediction of claustrophobia that one subject noted during testing with the mask.

In discussing the feasibility of using a new device in clinical anesthesia practice, cost must be a consideration. A company spokesman noted the retail unit cost of the CAPNOXYGEN™ mask is $3.95. A survey of three military hospitals in a metropolitan area found the average unit cost of a simple nasal cannula was $2.00, and the cost of a 16 guage intervenous angiocatheter was $.20. Thus cost differences are not substantial.

## Recommendations for Future Study.

Further study should include an effort to replicate this study in the clinical setting with a larger patient sample. A larger, more diverse patient sample would increase the generalizability of the results. In addition, the ability to correlate the $ETCO_2$ of the CAPNOXYGEN™ mask to a arterial blood gas sample ($PaCO_2$) would provide a more definitive means of determining the accuracy of this device to deliver oxygen and measure end-tidal carbon dioxide. An arterial blood gas would also provide strong evidence to correlate the $FIO_2$ and $SaO_2$ delivered by the two devices in this study.

A future study could also examine the correlation of $ETCO_2$ obtained by mask to other nasal cannula products designed to measure $ETCO_2$ during monitored anesthesia care procedures. One is the Nazorcap Sampler (NasOrCap Medical, Inc., West Mifflin, PA, 1998), noted in the review of the literature. Another new nasal cannula product

which could be tested is the MAC Safe nasal cannula (Vital Signs, Inc., Totowa, NJ 1999) which is currently in use in clinical practice. These tests could also compare the variables of fit, comfort and cost, which was not the primary aim of this study.

Finally, the $ETCO_2$ obtained by the CAPNOXYGEN™ mask could be compared to other noninvasive methods of measuring end-tidal carbon-dioxide which do not administer oxygen. One such method is the development of the transcutaneous carbon dioxide skin sensor placed on a patient during oxygen administration, which was tested in the Saunders et al. (1994) study.

This study demonstrated a strong association to the Betty Neuman Systems Model of stress and adaptation. A certified registered nurse anesthetist developed the CAPNOXYGEN™ mask to address physiologic and mechanical variables which affected the reliability of other methods of providing oxygen and monitoring $ETCO_2$ in spontaneously breathing patients. Future studies should consider the Neuman Model as a framework for evaluating the CAPNOXYGEN™ mask or other methods of oxygen delivery and $ETCO_2$ monitoring.

## Summary

This study showed a positive strong correlation between $ETCO_2$ measured by nasal cannula and CAPNOXYGEN™ mask with and without oxygen flow. Correlation was strongest and statistically significant without oxygen and at six liters per minute of oxygen flow. The nasal cannula provided a consistent mean $ETCO_2$ measurement during all levels of oxygen administration, while the CAPNOXYGEN™ mask showed significant dilution of $ETCO_2$ as oxygen flows increased. Differences in the delivered $FIO_2$ and resulting $SaO_2$ for each device were too small to warrant further analysis.

In considering the feasibility of using a new device in clinical practice, patient preference and cost are important considerations. In this study, a majority of study subjects preferred the fit and comfort of the CAPNOXYGEN™ mask over the nasal cannula during their testing experience. A telephone survey of three metropolitan military hospitals revealed the cost of the CAPNOXYGEN™ mask is slightly more expensive than the combined cost of a nasal cannula and 16-guage intervenous angiocatheter.

Future studies should consider the use of a larger patient sample which compares the $ETCO_2$ of the CAPNOXYGEN™ mask to $PaCO_2$ to definitively determine the accuracy of this device to deliver oxygen and measure end-tidal carbon dioxide. In addition, the $ETCO_2$ of the mask could be correlated to other nasal cannula products designed to measure $ETCO_2$ during monitored anesthesia care procedures.

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# APPENDICES

Appendix A

Health Survey Questionnaire

Research Study
THE CORRELATION BETWEEN END-TIDAL CARBON DIOXIDE MEASURED BY CAPNOXYGEN$^{TM}$ MASK AND NASAL CANNULA

As you have decided to volunteer to participate in the research study identified above, please answer the following health questions to the best of you ability by circling the appropriate answer.

1. Do you have any of the following respiratory conditions: emphysema, bronchitis, asthma, or any restrictive or obstructive illness that could affect the rate or depth of your breathing? YES NO

   If yes, please explain below.

2. In the last ten days, have you had any symptoms of a cold, cough, or influenza virus? YES NO

3. Do you smoke? YES NO

4. Do you have any limitations that would prevent you from breathing through your nose and mouth while wearing an oxygen mask or nasal cannula?
   YES NO

   If yes, please explain below.

Thank you for your cooperation in completing this questionnaire.

Appendix B

Informed Consent Form

Research Study
The Correlation Between End Tidal Carbon Dioxide Measured by CAPNOXYGEN™ Mask and Nasal Cannula

## Introduction

You are being asked to participate in a research study. Before you decide to a part of the research study, you need to understand the risks and benefits so that you can make an informed decision. This is known as informed consent.

This consent form provides information about the research study, which has been explained to you. Once you understand the study and the tests it requires, you will be asked to sign this form if you want to participate. Your decision to participate in the study is voluntary. This means that you are free to choose if you will take part in the study.

Purpose and Procedures

The Department of Nursing Anesthesia of the Uniformed Services University of the Health Sciences is carrying out this research study to test the accuracy of end-tidal carbon dioxide ($ETCO_2$) measurements obtained by a new oxygen mask produced by CAPNOXYGEN™ LLC. This study will correlate these measurements to $ETCO_2$ measurements obtained using a carbon dioxide ($CO_2$) sampling port inserted inside a nasal cannula commonly used in operating rooms during conscious sedation procedures. Fifteen volunteers will be asked to participate in this research study.

The procedure for this study includes the random application of either the CAPNOXYGEN™ mask over your nose and mouth, or a standard adult nasal cannula placed into your nares with a 16 gauge angiocatheter inserted through one of the prongs connected to a $CO_2$ sampling port. You will be asked breathe normally for two minutes to obtain baseline $ETCO_2$ measurements, and then oxygen will be administered in increments of 2, 4, and 6 liters per minute for a period of two minutes. At each level of oxygen administration, a average $ETCO_2$ reading will be taken from either the nasal catheter $CO_2$ sensor or CAPNOXYGEN™ mask port. Following a two-minute rest period, you will be asked to breathe normally with the second devise for two minutes, and then repeat the same sequence of oxygen administration and average $ETCO_2$ readings. After the procedure, you will be asked to complete a brief questionnaire regarding the comfort and fit of each devise

### Benefits

While there are no direct benefits to participating in the study, volunteers will be allowed to keep the CAPNOXYGEN™ mask following testing.

### Time Commitment

The entire procedure, including the completion of forms, should take no more than 30 minutes.

**Risks**

There are no risks identified in this study. The safety of nasal cannulas has been well documented in the literature. Literature from CAPNOXYGEN™ LLC claims there are no contraindications for its use on human subjects.

**Cost of Participation**

None to you.

**Alternatives**

The alternative is to not participate in this research study.

**Voluntariness**

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and you may discontinue participation at any time without penalty or loss of benefits. Inclusion criteria: Fifteen Nurse Anesthetist Student volunteers will be recruited to participate in this study. Exclusion criteria: Existing pulmonary disease of any kind, an upper respiratory infection within 10 days of testing, asthma, and smoking.

**Research Related Injury**

This study should no entail any physical or mental risk beyond those described above. We do not expect complications to occur, but if, for any reason, you feel that continuing this study would constitute a hardship for you, we will end you participation in the study.

DoD will provide medical care at government facilities for any DoD eligibles for injury or illness resulting from participation in this research. Such care may not be available to other research participants. Compensation may be available through judicial avenues to non-active duty research participants of they are injured through the negligence (fault) of the Government.

If at any time you believe you have suffered an injury or illness as a result of participating in this research project, you should contact the Office of Research Administration at the Uniformed Services University of the Health Sciences (USUHS), Bethesda, MD 20814 at (301) 295-3303. This office can review the matter with you, can provide information about your rights as a subject, and may be able to identify resources available to you. Information about judicial avenues of compensation is available from the University s General Counsel at (301) 295-3028.

**Confidentiality of Records**

All information that you provide as a part of this study will be confidential and will be protected to the fullest extent of the law. Information that you provide and other records related to this study will be kept private, accessible only to those persons directly involved in conducting this study and members of the Uniformed Services University of the Health Science s Institutional Review Board and other Federal agencies who provide

oversight for human use protection. All questionnaires and forms will be kept in a restricted access, locked cabinet while not in use. However, please be advised that under Federal Law, a military member s confidentiality cannot be strictly guaranteed. To enhance your privacy of the answers that you data from questionnaires will be entered into a database in which individual responses are no identified. After verification of the database information, the hard copy of the questionnaires containing identifiers will be shredded.

**Questions**

If you have any questions about this research study, you should contact LT Leo J. Fitzpatrick at 301-650-0009, or Maura S. McAuliffe, Ph.D., CRNA at 301-295-6565, chair of my thesis committee. If you have any questions about your rights as a research subject, you should call the Director of Research Programs in the Office of Research at USUHS at 301-295-3303. This person is your representative and has no connection to the researcher conducting this study.

I do hereby volunteer to participate in a research study entitled: THE CORRELATION BETWEEN END-TIDAL CARBON DIOXIDE MEASURED BY CAPNOXYGENTM MASK AND NASAL CANNULA. The implication of my voluntary participation: the nature, duration and purpose; the methods and measns by which it is to be conducted; and the inconveniences and hazards to be expected have been thoroughly explained to me by _____.

By signing this consent form you are agreeing that the study has been explained to you and that you understand this study. You are signing that you agree to take part in this study. You will be given a copy of this consent form.

I have been give the opportunity to ask questions concerning this study, and such questions have been answered to my full and complete satisfaction.

| | |
|---|---|
| _____ | _____ |
| Name (print) | Date |
| _____ | _____ |
| Signature | Date |
| _____ | _____ |
| Signature (witness) | Date |

I certify that the research study has been explained to the above individual, by me, and that the individual understands the nature and purpose , the possible risks and benefits associated the taking part in the research study. Any questions that have been raised have been answered.

| | |
|---|---|
| _____ | _____ |
| Investigator | Date |

Appendix C

Post-testing questionnaire

Research Study

THE CORRELATION BETWEEN END-TIDAL CARBON DIOXIDE MEASURED BY CAPNOXYGEN$^{TM}$ MASK AND NASAL CANNULA

Now that you have completed your participation in the study identified above, please answer the following questions regarding the comfort and fit of each devise used.

1. Which devise was more comfortable to wear during your testing experience? Why?

2. If this had been a conscious sedation or monitored anesthesia care procedure lasting more than one hour, which devise would you prefer to wear?

3. In your opinion, which devise provided the best fit for administering oxygen and measuring end-tidal carbon dioxide?

4. At rest, would you describe yourself as a nose breather or mouth breather?

5. When wearing the nasal cannula, did you deliberately try to breathe through your nose?

Any additional comments regarding your testing procedure?

Appendix D:  Data Analysis Tables by Subject

Data analysis table (per subject)
Subject #1

DEVICE: Nasal Cannula

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 95 | 18 | 42 |
| | 60 | 21 | 96 | 16 | 43 |
| | 90 | 21 | 96 | 16 | 44 |
| | 120 | 21 | 97 | 16 | 42 |
| | AVE. | | | | 42.75 |
| 2 | 30 | 22 | 97 | 28 | 44 |
| | 60 | 22 | 98 | 16 | 43 |
| | 90 | 22 | 98 | 16 | 44 |
| | 120 | 23 | 98 | 16 | 44 |
| | AVE. | | | | 43.75 |
| 4 | 30 | 30 | 99 | 15 | 44 |
| | 60 | 34 | 99 | 15 | 43 |
| | 90 | 29 | 99 | 16 | 42 |
| | 120 | 30 | 99 | 16 | 43 |
| | AVE. | | | | 43 |
| 6 | 30 | 39 | 98 | 17 | 42 |
| | 60 | 40 | 99 | 16 | 42 |
| | 90 | 37 | 99 | 16 | 43 |
| | 120 | 36 | 99 | 16 | 42 |
| | AVE. | | | | 42.25 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 96 | 15 | 42 |
| | 60 | 18 | 95 | 16 | 40 |
| | 90 | 19 | 96 | 14 | 41 |
| | 120 | 19 | 95 | 15 | 41 |
| | AVE | | | | 41 |
| 2 | 30 | 27 | 95 | 16 | 39 |
| | 60 | 28 | 95 | 14 | 39 |
| | 90 | 28 | 98 | 14 | 38 |
| | 120 | 28 | 98 | 14 | 37 |
| | AVE | | | | 38.25 |
| 4 | 30 | 32 | 98 | 18 | 37 |
| | 60 | 29 | 98 | 14 | 36 |
| | 90 | 33 | 99 | 15 | 34 |
| | 120 | 29 | 99 | 13 | 36 |
| | AVE | | | | 35.75 |
| 6 | 30 | 36 | 99 | 14 | 34 |
| | 60 | 37 | 99 | 15 | 35 |
| | 90 | 34 | 99 | 15 | 32 |
| | 120 | 41 | 99 | 13 | 36 |
| | AVE | | | | 34.25 |

DEVICE: CAPNOXYGEN mask

Data analysis table (per subject)
Subject #2

DEVICE: CAPNOXYGEN mask

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 99 | 10 | 42 |
| | 60 | 21 | 99 | 13 | 42 |
| | 90 | 21 | 99 | 12 | 39 |
| | 120 | 21 | 100 | 22 | 40 |
| | AVE. | | | | 40.75 |
| 2 | 30 | 30 | 100 | 8 | 39 |
| | 60 | 30 | 100 | 8 | 37 |
| | 90 | 28 | 100 | 10 | 35 |
| | 120 | 28 | 100 | 13 | 29 |
| | AVE. | | | | 35 |
| 4 | 30 | 34 | 100 | 9 | 36 |
| | 60 | 46 | 100 | 6 | 37 |
| | 90 | 37 | 100 | 7 | 36 |
| | 120 | 36 | 100 | 5 | 36 |
| | AVE. | | | | 36.25 |
| 6 | 30 | 44 | 100 | 18 | 35 |
| | 60 | 33 | 100 | 14 | 33 |
| | 90 | 43 | 100 | 21 | 28 |
| | 120 | 46 | 100 | 7 | 34 |
| | AVE. | | | | 32.5 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 99 | 22 | 36 |
| | 60 | 21 | 99 | 24 | 38 |
| | 90 | 20 | 99 | 22 | 35 |
| | 120 | 21 | 99 | 18 | 36 |
| | AVE | | | | 36.25 |
| 2 | 30 | 23 | 99 | 8 | 39 |
| | 60 | 24 | 100 | 7 | 39 |
| | 90 | 27 | 100 | 9 | 39 |
| | 120 | 23 | 100 | 8 | 39 |
| | AVE | | | | 39 |
| 4 | 30 | 31 | 100 | 8 | 39 |
| | 60 | 33 | 100 | 10 | 38 |
| | 90 | 24 | 100 | 9 | 40 |
| | 120 | 47 | 100 | 8 | 40 |
| | AVE | | | | 38 |
| 6 | 30 | 25 | 100 | 10 | 40 |
| | 60 | 24 | 100 | 9 | 38 |
| | 90 | 33 | 100 | 14 | 37 |
| | 120 | 32 | 100 | 9 | 39 |
| | AVE | | | | 37 |

DEVICE: Nasal Cannula

Data analysis table (per subject)
Subject # 3

DEVICE: CAPNOXYGEN mask

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 98 | 13 | 43 |
| | 60 | 21 | 98 | 16 | 34 |
| | 90 | 20 | 98 | 13 | 37 |
| | 120 | 21 | 98 | 8 | 41 |
| | AVE. | | | | 38.75 |
| 2 | 30 | 24 | 99 | 7 | 37 |
| | 60 | 24 | 99 | 7 | 37 |
| | 90 | 22 | 99 | 9 | 39 |
| | 120 | 24 | 99 | 8 | 38 |
| | AVE. | | | | 37.75 |
| 4 | 30 | 30 | 100 | 7 | 34 |
| | 60 | 28 | 100 | 17 | 32 |
| | 90 | 27 | 100 | 16 | 30 |
| | 120 | 25 | 100 | 9 | 31 |
| | AVE. | | | | 31.75 |
| 6 | 30 | 28 | 100 | 16 | 32 |
| | 60 | 39 | 100 | 17 | 32 |
| | 90 | 30 | 100 | 10 | 32 |
| | 120 | 30 | 100 | 16 | 33 |
| | AVE. | | | | 32.25 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 99 | 15 | 35 |
| | 60 | 21 | 99 | 23 | 38 |
| | 90 | 21 | 98 | 22 | 37 |
| | 120 | 21 | 99 | 14 | 37 |
| | AVE | | | | 36.75 |
| 2 | 30 | 21 | 99 | 22 | 36 |
| | 60 | 21 | 99 | 11 | 32 |
| | 90 | 21 | 99 | 19 | 31 |
| | 120 | 21 | 99 | 14 | 38 |
| | AVE | | | | 34.25 |
| 4 | 30 | 22 | 100 | 19 | 40 |
| | 60 | 24 | 100 | 13 | 37 |
| | 90 | 23 | 100 | 20 | 36 |
| | 120 | 25 | 99 | 14 | 39 |
| | AVE | | | | 38 |
| 6 | 30 | 31 | 100 | 15 | 41 |
| | 60 | 24 | 100 | 30 | 37 |
| | 90 | 31 | 100 | 17 | 41 |
| | 120 | 31 | 100 | 18 | 38 |
| | AVE | | | | 38.25 |

DEVICE: Nasal Cannula

Data analysis table (per subject)
Subject # 4

DEVICE: CAPNOXYGEN mask

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 100 | 17 | 40 |
| | 60 | 21 | 100 | 21 | 38 |
| | 90 | 21 | 100 | 13 | 41 |
| | 120 | 21 | 100 | 14 | 41 |
| | AVE. | | | | 40 |
| 2 | 30 | 28 | 100 | 10 | 38 |
| | 60 | 27 | 100 | 10 | 39 |
| | 90 | 29 | 100 | 10 | 38 |
| | 120 | 29 | 100 | 10 | 39 |
| | AVE. | | | | 38.5 |
| 4 | 30 | 35 | 100 | 11 | 36 |
| | 60 | 42 | 100 | 8 | 37 |
| | 90 | 40 | 100 | 8 | 36 |
| | 120 | 35 | 100 | 10 | 35 |
| | AVE. | | | | 36 |
| 6 | 30 | 33 | 100 | 12 | 34 |
| | 60 | 43 | 100 | 8 | 35 |
| | 90 | 43 | 100 | 7 | 35 |
| | 120 | 34 | 100 | 10 | 34 |
| | AVE. | | | | 34.5 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 100 | 12 | 38 |
| | 60 | 21 | 100 | 13 | 40 |
| | 90 | 21 | 100 | 15 | 38 |
| | 120 | 21 | 100 | 19 | 40 |
| | AVE | | | | 39 |
| 2 | 30 | 22 | 100 | 12 | 41 |
| | 60 | 23 | 100 | 13 | 41 |
| | 90 | 29 | 100 | 13 | 42 |
| | 120 | 22 | 100 | 11 | 40 |
| | AVE | | | | 41 |
| 4 | 30 | 39 | 100 | 10 | 40 |
| | 60 | 32 | 100 | 14 | 40 |
| | 90 | 33 | 100 | 12 | 41 |
| | 120 | 39 | 100 | 11 | 42 |
| | AVE | | | | 40.25 |
| 6 | 30 | 49 | 100 | 12 | 41 |
| | 60 | 49 | 100 | 9 | 40 |
| | 90 | 61 | 100 | 8 | 42 |
| | 120 | 51 | 100 | 9 | 41 |
| | AVE | | | | 41 |

DEVICE: Nasal Cannula

Data analysis table (per subject)
Subject # 5

DEVICE: Nasal Cannula

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 100 | 18 | 38 |
| | 60 | 21 | 100 | 15 | 37 |
| | 90 | 21 | 100 | 14 | 41 |
| | 120 | 21 | 100 | 15 | 40 |
| | AVE. | | | | 39 |
| 2 | 30 | 30 | 100 | 17 | 37 |
| | 60 | 30 | 100 | 11 | 38 |
| | 90 | 21 | 100 | 17 | 39 |
| | 120 | 22 | 100 | 25 | 41 |
| | AVE. | | | | 38.75 |
| 4 | 30 | 21 | 100 | 11 | 37 |
| | 60 | 23 | 100 | 6 | 40 |
| | 90 | 25 | 100 | 8 | 44 |
| | 120 | 41 | 100 | 7 | 44 |
| | AVE. | | | | 41.25 |
| 6 | 30 | 34 | 100 | 9 | 42 |
| | 60 | 46 | 100 | 9 | 43 |
| | 90 | 43 | 100 | 9 | 44 |
| | 120 | 44 | 100 | 9 | 36 |
| | AVE. | | | | 41.25 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 100 | 12 | 41 |
| | 60 | 21 | 100 | 8 | 43 |
| | 90 | 21 | 100 | 8 | 44 |
| | 120 | 20 | 100 | 12 | 39 |
| | AVE | | | | 41.75 |
| 2 | 30 | 26 | 100 | 13 | 37 |
| | 60 | 43 | 100 | 10 | 38 |
| | 90 | 31 | 100 | 5 | 43 |
| | 120 | 27 | 100 | 16 | 37 |
| | AVE | | | | 38.25 |
| 4 | 30 | 31 | 100 | 7 | 41 |
| | 60 | 34 | 100 | 7 | 40 |
| | 90 | 39 | 100 | 8 | 41 |
| | 120 | 40 | 100 | 8 | 42 |
| | AVE | | | | 41 |
| 6 | 30 | 33 | 100 | 7 | 40 |
| | 60 | 35 | 100 | 8 | 37 |
| | 90 | 31 | 100 | 12 | 40 |
| | 120 | 39 | 100 | 12 | 40 |
| | AVE | | | | 39.25 |

DEVICE: CAPNOXYGEN mask

Data analysis table (per subject)
Subject # 6

DEVICE: nasal cannula

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 20 | 98 | 12 | 46 |
| | 60 | 20 | 98 | 18 | 40 |
| | 90 | 20 | 99 | 15 | 42 |
| | 120 | 20 | 98 | 14 | 41 |
| | AVE. | | | | 42.25 |
| 2 | 30 | 23 | 99 | 13 | 42 |
| | 60 | 21 | 99 | 17 | 41 |
| | 90 | 21 | 100 | 15 | 40 |
| | 120 | 23 | 99 | 16 | 40 |
| | AVE. | | | | 40.75 |
| 4 | 30 | 30 | 100 | 14 | 41 |
| | 60 | 27 | 100 | 13 | 40 |
| | 90 | 29 | 100 | 6 | 41 |
| | 120 | 29 | 100 | 15 | 45 |
| | AVE. | | | | 41.75 |
| 6 | 30 | 34 | 100 | 14 | 42 |
| | 60 | 32 | 100 | 12 | 42 |
| | 90 | 33 | 100 | 14 | 42 |
| | 120 | 33 | 100 | 9 | 41 |
| | AVE. | | | | 42.5 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 100 | 13 | 40 |
| | 60 | 20 | 100 | 18 | 39 |
| | 90 | 20 | 100 | 13 | 42 |
| | 120 | 21 | 100 | 11 | 41 |
| | AVE | | | | 40.5 |
| 2 | 30 | 25 | 100 | 12 | 36 |
| | 60 | 27 | 100 | 14 | 37 |
| | 90 | 26 | 100 | 10 | 35 |
| | 120 | 27 | 100 | 15 | 37 |
| | AVE | | | | 36.25 |
| 4 | 30 | 32 | 100 | 15 | 35 |
| | 60 | 30 | 100 | 10 | 35 |
| | 90 | 39 | 100 | 14 | 35 |
| | 120 | 32 | 100 | 12 | 37 |
| | AVE | | | | 35.5 |
| 6 | 30 | 40 | 100 | 10 | 33 |
| | 60 | 41 | 100 | 14 | 35 |
| | 90 | 38 | 100 | 14 | 34 |
| | 120 | 37 | 100 | 5 | 32 |
| | AVE | | | | 33.5 |

DEVICE:

Data analysis table (per subject)
Subject # 7

DEVICE: CAPNOXYGEN mask

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 20 | 98 | 15 | 40 |
| | 60 | 21 | 100 | 17 | 40 |
| | 90 | 20 | 100 | 12 | 42 |
| | 120 | 21 | 100 | 11 | 43 |
| | AVE. | | | | 41.25 |
| 2 | 30 | 30 | 100 | 11 | 37 |
| | 60 | 29 | 100 | 16 | 35 |
| | 90 | 31 | 100 | 10 | 37 |
| | 120 | 32 | 100 | 11 | 36 |
| | AVE. | | | | 36.25 |
| 4 | 30 | 33 | 100 | 15 | 35 |
| | 60 | 33 | 100 | 14 | 34 |
| | 90 | 33 | 100 | 15 | 34 |
| | 120 | 34 | 100 | 11 | 34 |
| | AVE. | | | | 34.25 |
| 6 | 30 | 35 | 100 | 14 | 31 |
| | 60 | 37 | 100 | 14 | 30 |
| | 90 | 36 | 100 | 16 | 30 |
| | 120 | 37 | 100 | 17 | 31 |
| | AVE. | | | | 30.50 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 20 | 99 | 15 | 39 |
| | 60 | 21 | 99 | 19 | 40 |
| | 90 | 21 | 99 | 18 | 36 |
| | 120 | 20 | 99 | 20 | 41 |
| | AVE | | | | 39 |
| 2 | 30 | 24 | 100 | 17 | 40 |
| | 60 | 24 | 100 | 19 | 38 |
| | 90 | 23 | 100 | 13 | 41 |
| | 120 | 22 | 100 | 19 | 39 |
| | AVE | | | | 39.5 |
| 4 | 30 | 47 | 100 | 13 | 38 |
| | 60 | 41 | 100 | 21 | 39 |
| | 90 | 44 | 100 | 17 | 36 |
| | 120 | 38 | 100 | 21 | 34 |
| | AVE | | | | 36.75 |
| 6 | 30 | 56 | 100 | 19 | 28 |
| | 60 | 67 | 100 | 15 | 38 |
| | 90 | 59 | 100 | 20 | 36 |
| | 120 | 64 | 100 | 10 | 35 |
| | AVE | | | | 34.25 |

DEVICE: Nasal Cannula

Data analysis table (per subject)
Subject # 8

DEVICE: Nasal Cannula

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 100 | 8 | 38 |
| | 60 | 21 | 100 | 8 | 38 |
| | 90 | 21 | 100 | 9 | 39 |
| | 120 | 21 | 100 | 8 | 40 |
| | AVE. | | | | 38.75 |
| 2 | 30 | 23 | 100 | 10 | 40 |
| | 60 | 23 | 100 | 8 | 40 |
| | 90 | 24 | 100 | 8 | 39 |
| | 120 | 23 | 100 | 8 | 41 |
| | AVE. | | | | 40 |
| 4 | 30 | 28 | 100 | 10 | 37 |
| | 60 | 49 | 100 | 11 | 40 |
| | 90 | 33 | 100 | 13 | 39 |
| | 120 | 28 | 100 | 13 | 39 |
| | AVE. | | | | 38.75 |
| 6 | 30 | 46 | 100 | 9 | 37 |
| | 60 | 58 | 100 | 9 | 37 |
| | 90 | 50 | 100 | 13 | 37 |
| | 120 | 47 | 100 | 8 | 39 |
| | AVE. | | | | 37.5 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 20 | 99 | 17 | 37 |
| | 60 | 20 | 99 | 16 | 42 |
| | 90 | 20 | 99 | 15 | 41 |
| | 120 | 20 | 99 | 15 | 42 |
| | AVE | | | | 40.5 |
| 2 | 30 | 29 | 99 | 13 | 36 |
| | 60 | 30 | 100 | 10 | 36 |
| | 90 | 29 | 100 | 8 | 37 |
| | 120 | 30 | 100 | 14 | 36 |
| | AVE | | | | 36.25 |
| 4 | 30 | 46 | 100 | 11 | 34 |
| | 60 | 47 | 100 | 11 | 35 |
| | 90 | 35 | 100 | 12 | 34 |
| | 120 | 42 | 100 | 15 | 34 |
| | AVE | | | | 34.25 |
| 6 | 30 | 45 | 100 | 10 | 29 |
| | 60 | 46 | 100 | 10 | 31 |
| | 90 | 41 | 100 | 10 | 30 |
| | 120 | 49 | 100 | 8 | 29 |
| | AVE | | | | 29.75 |

DEVICE: CAPNOXYGEN mask

Data analysis table (per subject)
Subject # 9

DEVICE: Nasal Cannula

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 20 | 97 | 15 | 42 |
| | 60 | 21 | 96 | 11 | 43 |
| | 90 | 21 | 97 | 9 | 45 |
| | 120 | 21 | 97 | 10 | 44 |
| | AVE. | | | | 43.5 |
| 2 | 30 | 23 | 98 | 10 | 44 |
| | 60 | 21 | 99 | 8 | 44 |
| | 90 | 23 | 99 | 8 | 43 |
| | 120 | 22 | 99 | 9 | 44 |
| | AVE. | | | | 43.25 |
| 4 | 30 | 24 | 99 | 9 | 44 |
| | 60 | 23 | 99 | 8 | 46 |
| | 90 | 23 | 99 | 10 | 44 |
| | 120 | 24 | 99 | 11 | 46 |
| | AVE. | | | | 45 |
| 6 | 30 | 24 | 99 | 12 | 43 |
| | 60 | 27 | 100 | 14 | 43 |
| | 90 | 36 | 100 | 11 | 45 |
| | 120 | 25 | 99 | 18 | 42 |
| | AVE. | | | | 43.25 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 20 | 96 | 17 | 41 |
| | 60 | 20 | 97 | 14 | 42 |
| | 90 | 21 | 97 | 14 | 42 |
| | 120 | 20 | 98 | 10 | 42 |
| | AVE | | | | 41.25 |
| 2 | 30 | 27 | 97 | 14 | 37 |
| | 60 | 32 | 98 | 15 | 37 |
| | 90 | 31 | 98 | 13 | 35 |
| | 120 | 32 | 99 | 11 | 37 |
| | AVE | | | | 36.25 |
| 4 | 30 | 35 | 99 | 19 | 34 |
| | 60 | 33 | 99 | 13 | 35 |
| | 90 | 35 | 100 | 16 | 33 |
| | 120 | 48 | 99 | 12 | 34 |
| | AVE | | | | 34 |
| 6 | 30 | 36 | 97 | 16 | 32 |
| | 60 | 46 | 98 | 13 | 30 |
| | 90 | 42 | 99 | 15 | 34 |
| | 120 | 48 | 99 | 14 | 32 |
| | AVE | | | | 32 |

DEVICE: CAPNOXYGEN mask

Data analysis table (per subject)
Subject # 10

DEVICE: Nasal Cannula

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 100 | 17 | 35 |
| | 60 | 21 | 100 | 13 | 37 |
| | 90 | 21 | 100 | 15 | 37 |
| | 120 | 21 | 100 | 11 | 36 |
| | AVE. | | | | 36.25 |
| 2 | 30 | 23 | 100 | 10 | 39 |
| | 60 | 22 | 100 | 11 | 37 |
| | 90 | 23 | 100 | 9 | 40 |
| | 120 | 22 | 100 | 10 | 38 |
| | AVE. | | | | 38.5 |
| 4 | 30 | 23 | 100 | 9 | 39 |
| | 60 | 24 | 100 | 9 | 37 |
| | 90 | 25 | 100 | 9 | 38 |
| | 120 | 24 | 100 | 9 | 40 |
| | AVE. | | | | 38.5 |
| 6 | 30 | 30 | 100 | 9 | 39 |
| | 60 | 26 | 100 | 12 | 37 |
| | 90 | 37 | 100 | 7 | 38 |
| | 120 | 28 | 100 | 10 | 37 |
| | AVE. | | | | 37.75 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 100 | 13 | 36 |
| | 60 | 21 | 100 | 15 | 35 |
| | 90 | 21 | 100 | 14 | 36 |
| | 120 | 21 | 100 | 12 | 35 |
| | AVE | | | | 35.5 |
| 2 | 30 | 23 | 100 | 18 | 33 |
| | 60 | 31 | 100 | 12 | 32 |
| | 90 | 27 | 100 | 12 | 33 |
| | 120 | 27 | 100 | 12 | 32 |
| | AVE | | | | 32.5 |
| 4 | 30 | 37 | 100 | 17 | 33 |
| | 60 | 38 | 100 | 11 | 31 |
| | 90 | 38 | 100 | 14 | 32 |
| | 120 | 38 | 100 | 17 | 30 |
| | AVE | | | | 31.5 |
| 6 | 30 | 42 | 100 | 15 | 30 |
| | 60 | 45 | 100 | 14 | 29 |
| | 90 | 45 | 100 | 15 | 28 |
| | 120 | 41 | 100 | 15 | 30 |
| | AVE | | | | 29.25 |

DEVICE: CAPNOXYGEN mask

Data analysis table (per subject)
Subject # 11

DEVICE: CAPNOXYGEN mask

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 20 | 99 | 20 | 37 |
| | 60 | 20 | 99 | 11 | 41 |
| | 90 | 20 | 100 | 12 | 40 |
| | 120 | 20 | 100 | 13 | 41 |
| | AVE. | | | | 36.25 |
| 2 | 30 | 26 | 100 | 19 | 37 |
| | 60 | 27 | 100 | 9 | 37 |
| | 90 | 29 | 100 | 15 | 31 |
| | 120 | 28 | 100 | 13 | 37 |
| | AVE. | | | | 35.5 |
| 4 | 30 | 35 | 100 | 8 | 34 |
| | 60 | 36 | 100 | 15 | 35 |
| | 90 | 32 | 100 | 8 | 34 |
| | 120 | 33 | 100 | 12 | 33 |
| | AVE. | | | | 34 |
| 6 | 30 | 36 | 100 | 12 | 32 |
| | 60 | 42 | 100 | 14 | 31 |
| | 90 | 39 | 100 | 12 | 31 |
| | 120 | 40 | 100 | 18 | 30 |
| | AVE. | | | | 31.5 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 100 | 12 | 38 |
| | 60 | 20 | 100 | 15 | 33 |
| | 90 | 21 | 100 | 11 | 39 |
| | 120 | 21 | 100 | 16 | 36 |
| | AVE | | | | 36.5 |
| 2 | 30 | 24 | 100 | 12 | 40 |
| | 60 | 23 | 100 | 11 | 36 |
| | 90 | 24 | 100 | 10 | 36 |
| | 120 | 22 | 100 | 12 | 39 |
| | AVE | | | | 37.75 |
| 4 | 30 | 23 | 100 | 17 | 37 |
| | 60 | 31 | 100 | 9 | 39 |
| | 90 | 44 | 100 | 19 | 39 |
| | 120 | 67 | 100 | 21 | 37 |
| | AVE | | | | 38 |
| 6 | 30 | 56 | 100 | 10 | 36 |
| | 60 | 40 | 100 | 20 | 31 |
| | 90 | 35 | 100 | 9 | 39 |
| | 120 | 59 | 100 | 10 | 35 |
| | AVE | | | | 35.25 |

DEVICE: Nasal Cannula

Data analysis table (per subject)
Subject # 12

DEVICE: CAPNOXYGEN mask

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 97 | 12 | 45 |
| | 60 | 21 | 96 | 13 | 44 |
| | 90 | 21 | 96 | 10 | 46 |
| | 120 | 21 | 96 | 11 | 45 |
| | AVE. | | | | 45 |
| 2 | 30 | 29 | 97 | 10 | 39 |
| | 60 | 30 | 98 | 12 | 38 |
| | 90 | 30 | 99 | 13 | 38 |
| | 120 | 30 | 99 | 11 | 39 |
| | AVE. | | | | 38.5 |
| 4 | 30 | 35 | 99 | 13 | 36 |
| | 60 | 36 | 99 | 12 | 35 |
| | 90 | 35 | 100 | 10 | 37 |
| | 120 | 33 | 100 | 13 | 35 |
| | AVE. | | | | 35.75 |
| 6 | 30 | 38 | 99 | 10 | 32 |
| | 60 | 40 | 99 | 13 | 33 |
| | 90 | 46 | 99 | 12 | 33 |
| | 120 | 41 | 99 | 10 | 33 |
| | AVE. | | | | 32.75 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 97 | 14 | 43 |
| | 60 | 21 | 97 | 11 | 41 |
| | 90 | 21 | 97 | 12 | 45 |
| | 120 | 21 | 96 | 14 | 44 |
| | AVE | | | | 43.25 |
| 2 | 30 | 22 | 97 | 12 | 45 |
| | 60 | 21 | 98 | 13 | 46 |
| | 90 | 21 | 98 | 13 | 47 |
| | 120 | 22 | 98 | 12 | 46 |
| | AVE | | | | 46 |
| 4 | 30 | 24 | 98 | 9 | 47 |
| | 60 | 22 | 99 | 11 | 47 |
| | 90 | 23 | 99 | 10 | 47 |
| | 120 | 23 | 99 | 10 | 48 |
| | AVE | | | | 47.25 |
| 6 | 30 | 24 | 99 | 11 | 47 |
| | 60 | 24 | 99 | 12 | 46 |
| | 90 | 25 | 99 | 14 | 46 |
| | 120 | 24 | 99 | 10 | 47 |
| | AVE | | | | 46.25 |

DEVICE: Nasal Cannula

Data analysis table (per subject)
Subject # 13

DEVICE: CAPNOXYGEN mask

| $O_2$ L/M | TIME sec | $FIO_2$ | $SaO_2$ | RR | $ETCO_2$ |
|---|---|---|---|---|---|
| 0 | 30 | 21 | 97 | 12 | 45 |
| | 60 | 21 | 96 | 13 | 44 |
| | 90 | 21 | 96 | 16 | 46 |
| | 120 | 21 | 96 | 11 | 45 |
| | AVE. | | | | 45 |
| 2 | 30 | 30 | 97 | 12 | 39 |
| | 60 | 31 | 98 | 10 | 38 |
| | 90 | 30 | 99 | 13 | 38 |
| | 120 | 30 | 99 | 11 | 39 |
| | AVE. | | | | 38.5 |
| 4 | 30 | 35 | 99 | 13 | 36 |
| | 60 | 36 | 99 | 12 | 35 |
| | 90 | 35 | 99 | 10 | 37 |
| | 120 | 34 | 99 | 13 | 35 |
| | AVE. | | | | 35.75 |
| 6 | 30 | 38 | 100 | 10 | 32 |
| | 60 | 40 | 100 | 12 | 33 |
| | 90 | 46 | 99 | 14 | 33 |
| | 120 | 41 | 100 | 13 | 33 |
| | AVE. | | | | 32.75 |
| $O_2$ L/M | TIME sec | $FIO_2$ | $SAO_2$ | RR | $ETCO_2$ |
| 0 | 30 | 21 | 97 | 14 | 43 |
| | 60 | 21 | 98 | 11 | 41 |
| | 90 | 21 | 99 | 12 | 45 |
| | 120 | 21 | 98 | 14 | 44 |
| | AVE | | | | 43.25 |
| 2 | 30 | 22 | 97 | 12 | 45 |
| | 60 | 21 | 98 | 13 | 46 |
| | 90 | 21 | 98 | 13 | 47 |
| | 120 | 22 | 98 | 12 | 46 |
| | AVE | | | | 46 |
| 4 | 30 | 24 | 98 | 10 | 47 |
| | 60 | 22 | 99 | 12 | 47 |
| | 90 | 23 | 99 | 10 | 47 |
| | 120 | 23 | 99 | 12 | 48 |
| | AVE | | | | 47.25 |
| 6 | 30 | 25 | 99 | 11 | 47 |
| | 60 | 24 | 99 | 12 | 46 |
| | 90 | 25 | 99 | 13 | 46 |
| | 120 | 24 | 99 | 10 | 48 |
| | AVE | | | | 46.75 |

DEVICE: Nasal Cannula